

Appl. No. 10/036,308
Amendment dated October 7, 2003
Reply to Office Action of April 7, 2003

This listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

- 1-3. (Cancelled)
4. (Currently amended) A method for diagnosing ~~and monitoring~~ Alzheimer's disease ~~as claimed in claim 1~~ comprising:
- (a) obtaining ~~serum~~ blood or cerebrospinal fluid from a subject;
 - (b) detecting the amount of human kallikrein 6 ("hK6") in said ~~serum~~ blood or cerebrospinal fluid; and
 - (c) comparing said amount of hK6 detected to ~~a standard~~ an amount for healthy control subjects, where detection of a statistically significant increase level of hK6 ~~greater than that of a standard compared with an amount for the healthy control subjects~~ is indicative of Alzheimer's ~~[[D]]~~ disease.
5. (Currently amended) A method for diagnosing ~~and monitoring~~ Alzheimer's ~~[[D]]~~ disease as claimed in claim ~~[[1]]~~ 4 comprising:
- (a) ~~contacting a biological sample from a subject~~ the blood or cerebrospinal fluid with an antibody specific for hK6 which is directly or indirectly labelled with a detectable substance;
 - (b) quantifying hK6 by detecting the detectable substance to quantitate hK6 in the sample the blood or cerebrospinal fluid;
 - (c) comparing the quantitated level of hK6 to levels obtained for samples from healthy control subjects ~~or from other samples of the subject~~ where a statistically significant increase in the hK6 levels compared with levels for the healthy control subjects is indicative of Alzheimer's disease.

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6. (Currently amended) A method for the diagnosis and monitoring of Alzheimer's ~~[[D]]~~disease as claimed in claim ~~[[1]]~~ 4 comprising
- (a) incubating ~~a biological sample from a subject~~ the blood or cerebrospinal fluid with a first antibody specific for hK6 which is directly or indirectly labeled with a detectable substance, and a second antibody specific for hK6 which is immobilized;
 - (b) separating the first antibody from the second antibody to provide a first antibody phase and a second antibody phase;
 - (c) quantitating hK6 by detecting the detectable substance in the first or second antibody phase ~~thereby quantitating hK6 in the biological sample~~; and
 - (d) comparing the quantitated hK6 with quantitated levels obtained for samples from healthy control subjects ~~or from other samples of the subject where a statistically significant increase in hK6 levels compared with levels for the healthy control subjects is indicative of Alzheimer's disease.~~

7-8. (Cancelled)

9. (Currently amended) A method as claimed in claim 6 wherein in step (a) the first and second antibodies are contacted simultaneously or sequentially with the ~~biological sample~~ blood or cerebrospinal fluid.

10. (Currently amended) A method as claimed in claim ~~[[2]]~~ 5 wherein the antibody is a monoclonal antibody, a polyclonal antibody, immunologically active antibody fragments, humanized antibody, an antibody heavy chain, an antibody light chain, a genetically engineered single chain F_v molecule, or a chimeric antibody.

11. (Previously presented) A method as claimed in claim 5 wherein the detectable substance is alkaline phosphatase.

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12. (Previously presented) A method as claimed in claim 11 wherein the alkaline phosphatase is detected using a fluorogenic substrate.

13. (Currently amended) A method as claimed in claim 12 wherein hK6 is ~~measured~~ detected using time-resolved fluorescence.